

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

V.

(1) STRYKER BIOTECH, LLC,

(2) MARK PHILIP,

(3) WILLIAM HEPPNER,

(4) DAVID ARD and

(5) **JEFFREY WHITAKER,**

Defendants.

Criminal No: 09-CR-10330-GAO

**DEFENDANT STRYKER BIOTECH'S MEMORANDUM OF LAW
IN SUPPORT OF MOTION TO SEVER COUNT 15**

Pursuant to Rule 8(a) of the Federal Rules of Criminal Procedure, Defendant Stryker Biotech, LLC (“Biotech”) respectfully submits this Memorandum of Law in support of its motion to sever Count 15 of the Indictment from Counts 1-14. Biotech joins in Defendants William Heppner, David Ard and Jeffrey Whitaker’s (collectively, the “Individual Defendants”) motion to sever under Rules 8(b) and 14.¹ As the sole defendant named in all counts but for Counts 13 and 14, Biotech hereby moves separately under Rule 8(a) for severance.

In its Indictment, the Government alleges a scheme to defraud surgeons by Biotech, Mark Philip and the Individual Defendants through the fraudulent co-promotion of OP-1 Putty or OP-1 Implant (“OP-1”) with Calstrux. These allegations form the basis for the first fourteen counts of

¹ The Individual Defendants have filed a motion to sever Count 15 under Rule 8(b) and Rule 14. Rule 8(b) governs the joinder of defendants and sets forth the standard for determining severance of counts in a multiple-defendant indictment. *See United States v. Natanel*, 938 F.2d 302 (1st. Cir. 1991). If the Court grants the Individual Defendants' motion to sever under Rule 8(b) or Rule 14, the Court does not need to decide this motion.

the Indictment. All five defendants are charged in Counts 1-14.² In Count 15, the Government introduces an entirely new set of facts charging an offense against Biotech that does not involve allegations concerning Biotech's promotional practices, the combined use of OP-1 and Calstrux, or an intent to defraud surgeons. Biotech is the only defendant charged in Count 15. None of the individual defendants are included in this false statement charge. Count 15, the false statement count, stands alone in both the alleged premise and the character of the claim, charging that Biotech falsely reported to the FDA in an annual report regarding the number of patients treated with OP-1 Putty.³ The Indictment does not allege any connection between Count 15 and the preceding 14 counts. Because Count 15 is not part of a "common scheme or plan" or "of the same or similar character" as Counts 1-14, joinder of the counts is improper under Rule 8(a) and severance of the charge is the appropriate remedy.

In addition to being impermissible under Rule 8(a), the joinder of Counts 1-14 with Count 15 will increase the length of the trial. The Individual Defendants have moved, under Rule 8(b) and Rule 14, to sever Count 15, in part, because of the prejudice that they will face due to negative spillover from the allegations in Count 15 and the increased likelihood of juror confusion given the complexity that trying Count 15 will involve. Even without Count 15, the trial is estimated to last 6 weeks and will involve complex legal issues, expert testimony from doctors and regulators and more than 30 fact witnesses. If the Court rules to sever Count 15 from the preceding counts, as a practical matter, the jury trial will be streamlined. Biotech is willing to try Count 15 separately to the Court and expects that the parties could stipulate to several facts.

² All five defendants are charged in Counts 1-6. Biotech is charged in Counts 7-12. David Ard is charged in Count 13 and Jeffrey Whitaker is charged in Count 14.

³ The Government has filed an assented-to motion to dismiss Count 16.

I. Joinder of Counts 1-14 and Count 15 is Improper and, Therefore, Count 15 Should Be Severed for Purposes of Trial.

Under Federal Rule of Criminal Procedure Rule 8(a), joinder of two or more offenses in an Indictment is proper “if the offenses charged . . . (1) are of the same or similar character, or (2) are based on the same act or transaction, or (3) are connected with or constitute parts of a common scheme or plan.” Fed. R. Crim. P. 8(a). A plausible basis for joinder of multiple counts should be discernible from the face of the indictment. *United States v. Fenton*, 367 F.3d 14, 22 (1st Cir. 2004) *citing United States v. Natanel*, 938 F.2d 302 (1st Cir. 1991). Where there is a finding of misjoinder prior to trial, the appropriate remedy is severance. *See United States v. Capozzi*, 73 F. Supp. 2d 75, 81 (D. Mass. 1999) (finding misjoinder and ordering severance of three counts where the only commonality was involvement of the same gun).

A. Count 15 is Not Based on the Same Act or Transaction, Nor Is It Connected with or Part of the Common Scheme Alleged in Counts 1-14.

Not only are Counts 1-14, charging fraudulent co-promotion to surgeons, and Count 15, charging submission of one false statement to the FDA in an annual report, not based on the same act or transaction, there is no discernible connection evident in the Indictment between the alleged acts underlying the counts. The rule of joinder is not “a license to join any and all charges made against a single defendant, no matter what their interconnection.” *United States v. Buchanan*, 930 F.Supp. 657, 662 (D. Mass 1996). To be “connected together,” the charged offenses must “grow out of related transactions.” *Id.*, *citing e.g. United States v. Randazzo*, 80 F.3d 623, 627 (1st Cir. 1996).

Counts 1-14 and Counts 15 are alleged to have arisen out of unconnected transactions. In Counts 1-5, the wire fraud counts, the Defendants are charged with a scheme to defraud “physicians and hospitals” by allegedly misleading them about the efficacy, approval status, and

nature of OP-1 and Calstrux. *See, e.g.*, Indictment ¶ 42, 48. Similarly, in Count 6, the conspiracy count, the Defendants are charged with conspiring to defraud the FDA through the “deliberate manipulation of surgeons and surgical staff into using an unapproved mixture of OP-1 with Calstrux.” *Id.* ¶¶ 60-61. As part of the overt acts of this alleged conspiracy, Defendants allegedly distributed “recipes” for mixing OP-1 and Calstrux. *Id.* ¶ 63(g)(1)-(8). Finally, in Counts 7-14, the alleged distribution of these same “recipes” is charged as substantive violations of the Federal Food, Drug, and Cosmetic Act (“FDCA”). *Id.* ¶ 64-69.

Count 15, in contrast, charges Biotech alone with “knowingly and willfully mak[ing] a materially false statement” on April 30, 2007 regarding the number of patients treated by OP-1 Putty during the preceding 12 months. The Indictment does not allege that the conduct detailed in Counts 15 was an overt act of the conspiracy alleged in Count 6, nor does it allege that this activity had anything to do with the scheme to defraud alleged in Counts 1-5 or the misbranding charges levied in Counts 7-14. *Cf. United States v. Fenton*, 367 F.3d 14, 21 (1st Cir. 2004) (finding joinder of pipe bomb and drug-trafficking counts was proper where “the indictment charged” use of the pipe bomb “in furtherance of the drug-trafficking conspiracy”).

In addition, the critical evidence that the Government would need to present at trial to prove the fraudulent co-promotion charges does not overlap with the evidence necessary to prove the single false statement charge. *Randazzo*, 80 F.3d at 628 (“Congress did not provide for joinder for unrelated transactions . . . merely because some evidence might be common to all of the counts.”). In order to prove the Section 1001(a)(2) violation alleged in Count 15, the Government must prove that (i) Biotech made a statement to the FDA; (ii) the statement was both false and material and (iii) Biotech had knowledge that it was false at the time the statement was made. None of the evidence necessary to prove these elements is central to proving the fraudulent co-promotion counts, or even relevant from the face of the Indictment. For Count 15,

the Government intends to introduce the testimony of the Biotech employee who signed the allegedly inaccurate annual report, Donna Supko. Ms. Supko will be called solely for Count 15 and her testimony will have no relevance to the other fraudulent co-promotion counts.

Buchanan, 930 F. Supp. at 663 n. 15, citing *United States v. Windom*, 19 F.3d 1190, 1196 (7th Cir. 1994) (Offenses are sufficiently connected “where proof of one crime ‘constitutes a substantial portion of the proof of the other.’”). Thus, joinder of these two distinct sets of charges is improper.

The First Circuit was presented circumstances on all fours with the facts presented here in *United States v. Randazzo*, 80 F.3d 623, 626 (1st Cir. 1996). In *Randazzo*, the Government joined FDCA counts with false statement counts in the same indictment. The First Circuit held that the counts were not properly joined under Rule 8(a). In *Randazzo*, the Government charged a shrimp company and its president with 97 counts related to the sale of adulterated shrimp and the president alone with four counts of filing false tax returns. *Id.* at 626. The “shrimp” counts, like the fraudulent co-promotion counts here, included conspiracy counts under 18 U.S.C. § 371 and FDCA counts under 21 U.S.C. § 331(k). The essence of these charges was that the company and its president used prohibited and undisclosed substances in producing shrimp in order to alter its color and thereby increase its value. *Id.* The tax charges, like the false statement charge here, involved false statements contained in a government filing, and alleged that the president caused the company to file false tax returns overstating expenses. *Id.*

Under the “common scheme” prong of Rule 8(a), the government in *Randazzo* argued that the counts against the president were properly joined because they involved a “common scheme or plan” to fraudulently report the company’s financial condition in order to conceal the fraudulent income obtained from the sale of the adulterated shrimp. *Id.* at 627. The First Circuit rejected this argument, finding that a plan to claim false corporate expenses was insufficiently

connected to a plan to increase revenue through selling adulterated shrimp. *Randazzo*, 80 F.3d at 627 (noting that “it was pure happenstance whether the overstated expenses happened to reduce legal income or illegal income of the Company”). In other words, because the president did not specifically conceal the illegal income, there was no clear connection between the tax charges and the alleged adulterated sales.

Similarly, here, any alleged plan to falsely report the number of patients treated by OP-1 Putty from April 30, 2006 to April 30, 2007, regardless of whether the patients were treated with OP-1 Putty as a result of fraudulent co-promotion of OP-1 Putty with Calstrux or not, is not part of the alleged scheme to fraudulently promote the combined use of these products. In fact, there is no allegation in the Indictment of a single scheme or of *any* connection between the two alleged schemes whatsoever. See *United States v. Fenton*, 367 F.3d 14, 22 (1st Cir. 2004) *citing* *United States v. Natanel*, 938 F.2d 302 (1st Cir. 1991) (holding that a plausible basis for joinder of multiple counts should be discernible from the face of the indictment).

B. Count 15 is Not of a Similar Character to Counts 1-14.

Whether the fraudulent co-promotion counts may be joined to the one false statement count, under Rule 8(a), because they are of a “similar character” is determined by a multifactor test. In weighing joinder, a court examines: “whether the charges are laid under the same statute, whether they involve similar victims, locations, or modes of operation, and the time frame in which the charged conduct occurred.” *United States v. Edgar*, 82 F.3d 499, 503 (1st Cir. 1996) *quoting* *United States v. Taylor*, 54 F.3d 967, 973 (1st Cir. 1995). Moreover, a connection in time alone is insufficient to justify joinder. *Buchanan*, 930 F. Supp. at 664.

The one false statement count does not share a common statutory underpinning, will not be proven by overlapping evidence, *see supra* at 4-5, and does not involve common victims, locations, or modes of operation. In contrast with Counts 1-14, which focus on the Defendants’

alleged means of promoting the combination of OP-1 with Calstrux by Biotech's *sales force* to *doctors practicing across the nation*, Count 15 focuses on one submission made to the *FDA* by one person in the Biotech *regulatory affairs department*, who worked in *Hopkinton, Massachusetts*.⁴

Any suggestion that Counts 1-14 and Count 15 are linked merely because the counts involve conduct regulated by the FDA is simply too tangential to satisfy Rule 8(a). "If subject matter similarity alone were sufficient, wholly unrelated charges ... could be deemed to be of same or similar character To extend the rule so broadly would lead to absurd results. . . ." *See United States v. Jawara*, 462 F.3d 1173, 1182-86 (9th Cir. 2006), *amended and superseded on other grounds*, 474 F.3d 565 (9th Cir. 2007) (finding that the fact that both counts involved immigration counts was insufficient to satisfy the "similar character" prong of Rule 8(a)); *see also Buchanan*, 930 F.Supp. at 662 (holding that a vague thematic commonality between two charges is insufficient to allow for joinder under the Rule).

Randazzo is also instructive in analyzing the facts of this case under the "similar character" prong. In *Randazzo*, the government argued that the "shrimp" and tax charges were of the "'same or similar character' because . . . both sets of offenses involved the use of falsehoods or omissions to profit at the expense of the federal government." *Randazzo*, 80 F.3d at 627. The government further noted facts common to both sets of charges, including overlapping time frames, the defendant's control over the company as a common means, and the company's sagging financial condition as a common motive. *Id.* Rejecting the government's argument, the First Circuit held, "it is very hard to describe adulterating or mislabeling shrimp as offenses 'similar' to tax fraud-except at a level of generality so high as to drain the term of any

⁴ Count 6, the conspiracy count, is a count to defraud the FDA. However, the manner and means of the conspiracy focuses solely on fraudulent off-label promotion to doctors.

real content.” *Id.* at 628. Similarly here, despite overlapping time periods and an attenuated factual connection, sales representatives fraudulently promoting a combination of three medical devices to surgeons and one regulatory affairs employee filing false statistics associated with use of one medical device to the FDA cannot be said to be of similar character.

II. Severance Will Conserve Judicial Resources.

In some instances, joinder of counts may conserve judicial resources. However, in this case, because of the length and complexity of the case when Count 15 is joined with the preceding 14 counts, it is in the interests of judicial economy to sever Count 15 and shorten the five-defendant trial.

Biotech is willing to have Count 15 tried by the Court outside the presence of the jury. Such a proposal would resolve the improper Rule 8 joinder issue and the serious prejudice to the Individual Defendants under Rule 14. Biotech anticipates it would be able to stipulate to several factual issues surrounding Count 15, leaving the Court to decide the narrow issues of intent and materiality, the former of which will likely turn on the predicate legal question of whether the concepts of “collective intent” and “collective knowledge” apply to a Section 1001 prosecution. To the extent that any particular witness called on the promotion side of the case had testimony relevant to Count 15, the Court could hear that testimony in the afternoon after the jury has been dismissed for the day. Biotech has submitted this proposal to the Government, but it has declined to pursue a bench trial on Count 15. A straight severance and brief trial on Count 15 at a later date is also a viable option. As a practical matter, it is unlikely a separate trial on Count 15 would ever actually be required. If the Government prevails against Biotech on the wire fraud, conspiracy, or felony misbranding counts,⁵ there would be no real reason to try Biotech for the false statement crime alleged in Count 15. On the other hand, if Biotech is fully acquitted on

⁵ Defendants have moved for the dismissal of the substantive felony misbranding counts for lack of venue.

the wire fraud, conspiracy, and felony misbranding counts, the company is optimistic that a resolution could be reached with the Government on what would be the sole remaining count.

CONCLUSION

For the foregoing reasons, Biotech respectfully requests that this Court grant the accompanying Motion to Sever Count 15 from the remainder of the charged Counts, and order separate trials.

Respectfully submitted,

STRYKER BIOTECH, LLC

/s/ Joshua Levy

Brien T. O'Connor (BBO #546767)

Joshua S. Levy (BBO #563017)

Ropes & Gray, LLP

800 Boylston St.

Boston, MA 02199

617-951-7000

Brien.O'Connor@ropesgray.com

Joshua.Levy@ropesgray.com

Dated: September 14, 2011

LOCAL RULE 7.1(A)(2) CERTIFICATION

I hereby certify that I contacted Assistant United States Attorney Susan Winkler by telephone to ask the Government's position on this motion. Assistant United States Attorney Winkler responded that the Government opposes it.

/s/ Joshua S. Levy
Joshua S. Levy

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and that paper copies will be sent to any indicated as non-registered participants, on September 14, 2011.

Dated: September 14, 2011

/s/ Joshua S. Levy
Joshua S. Levy